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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/870,321	LEHMANN, VOLKER	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 7-16-07.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 35-48 is/are pending in the application.

4a) Of the above claim(s) 47 and 48 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 35-46 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

microporous membrane 40 above the glass fiber filter chamber 11. The microporous membrane has a diameter greater than the glass fiber filter chamber, and the periphery of the microporous membrane 40 is nipped by the step portion 19 formed on the foundary between the glass fiber filter chamber 11 and the microporous membrane chamber 12 and the bottom of the cap 20 so as not to form a leakage without passing the blood filtering material.

As disclosed in the examples suction was carried out by using a peristaltic pump at a suction pressure (pressure difference) of 300 mm Hg at the maximum for a suction period of 15 seconds.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, Telework Thurs., 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 16, 2007 has been entered.

Election/Restrictions

2. Newly submitted claims 47-48 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims require a new element, control measure, not previously required or considered in the previous claims. As indicated by applicant a controller is not essential as such the method or process of controlling can be performed by other means such as manually by an operator.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 47-48 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

3. Applicant's arguments filed July 16, 2007 have been fully considered but they are not persuasive.

It should be noted that the additional clause "for taking up the medium to be analyzed" is not further structurally limiting but is directed to the intended use of the pipette. It is only required that the pipette be capable of aspirating a "medium" (non-specified substance). As to what one intends to do or with the medium is not a structural limitation of the apparatus/pipette.

In view of applicant's remarks, a controller measure is non-essential/non-critical and the action of controlling the pressure is not limited to the use of a controller. The previous 112 rejection directed thereto is hereby withdrawn.

As to applicant's argument that the examiner must consider the function of the pump having the ability to produce a negative pressure that does not exceed the critical pressure of liquid. The examiner has previously taken such function in consideration clearly explained such a function as claimed is interpreted. While the claim further relates the pumps ability to a critical pressure, there is no numerical value (psi, kpa, atm., torr, etc) given as for one to ascertain or determine what is the value of such critical pressure, thereby determining the specific limitations of the pump. The cited critical pressure would be dependent upon a number of factors (as supported by a the equation cited in the claims), including but not limited to a specific liquid and its chemical and physical characteristics, the size of the one pore, the physical and chemical characteristics of the diaphragm, the environmental pressure in which one

actually performs the "taking up" or aspiration. Considering such, as previously stated any pump structurally capable of generating a negative pressure (manually or automatically) in a pipette would be considered equivalent to the element as claimed. As long as a pump is present and can be controlled to produce a negative pressure, it meets the limitation. Broadly reciting a critical pressure of a liquid, could be any pressure of any liquid depending on such factors (as recited above). The critical pressure of water maybe different than the critical pressure of another liquid such as oil. The critical pressure of water may be different in when varying such factors as mentioned. The critical pressure could be 1 psi to any other value and since applicant has not provided any information as to determine what the critical pressure is limited to it is only required the pump be capable of producing a negative pressure sufficient to aspirate any liquid.

Applicant asserts claims 39 and 45 were amended to remove the negative limitation. Claim 39 was not amended as such.

Applicant continuously assert the equation of claims 37 and 43 is a functional limitation, the examiner respectfully disagrees. As stated above there are no numerical values given for the critical pressure. Furthermore the equation does not describe a physical/structural limitation of the device. The pressure is directed to an unspecified liquid substance and would vary as recited above. A device meeting the limitations of the independent claims as considered above is considered to follow such an equation as recited.

As to claims 38-39 and 44-45 applicant states: "The Examiner's comments have been noted and claims 38-39 and 44-45 haven been appropriately amended to positively introduce a medium to be analyzed."

Claims 38-39 were only amended by deleting word capillary. As such, the claims are not further structurally limiting as previously claimed for the "medium" is not an element of the apparatus. It is only required the device be capable of taking up or aspirating a liquid and gas.

As to claims 44-45, there is no actual positive step recited in the method of taking up or aspirating a medium. Furthermore while the medium is intended be analyzed there is no positive step recited to analyze the medium. How, when, where, who, or what performs analysis of the medium.

Applicant asserts the method is supported by paragraph 0086. The claims do not appear to be commensurate in scope with that of the paragraph. It appears the method consists of the steps of providing a pipette including at a distal end a diaphragm having at least one pore, submerging the pipette in a first medium/liquid held in a container, taking up/aspirating the entire amount of first medium/liquid in the container by applying negative pressure to the pipette (which would mean the critical pressure of the first medium/liquid is overcome) by way of a pump connected thereto, and further holding the aspirated liquid by controlling the pump such that adequate pressure is applied to the first medium/liquid such that it does not exit the pipette via the at least one pore nor allow a second medium/gas/air in the container enter the at least one pore.

The method claim as presently drafted while reciting the pipette is intended for taking up a medium does not positively recite a step that requires the actual aspiration/taking up of a medium/liquid. The first step as claimed on requires one to provide a pipette having a diaphragm having at least one pore of a given radius that is structurally capable of taking up a medium. The second step only requires producing a negative pressure that does not overcome a liquid present at the pore. It is unclear if the medium of the first step is the same as the liquid referenced in the second step. Furthermore it is not specified where the liquid is located in reference to the pore. The phrase "at the pore" could have various interpretations. No liquid or medium has been positively recited as being previously aspirated or taken up in the pipette. As such, one would assume the liquid is on the exterior of the pipette in the container but at the pore/container interface rather than the pore interface within the interior of the pipette. As such, it appears as if applicant is claiming providing a pipette with diaphragm having a pore of a given radius, and producing or applying via pump a negative pressure sufficient to aspirate a liquid through the pore and into the pipette (if the applied pressure is sufficient to aspirate the liquid, then inherently it is greater that the critical pressure (does not go below the critical pressure) or overcomes the surface tension of the liquid). A teaching of aspirating a liquid from a source into a pipette including a diaphragm having at least one pore would be equivalent to the method as claimed in claim 41.

As to claims 39 (not amended) and claim 45, as recited above the medium is not an element of the apparatus. In terms of the method, the medium is never recited as

being aspirated. Even if the medium were positively recited as being taken up, the pressure produced is recited as not going below the critical pressure of a liquid. If view of such if the one took up a gas the liquid would also be aspirated for the pressure produced is greater than the critical pressure of the liquid. Which is opposite of what applicant asserts is the invention and not supported by paragraph 0098.

It should be noted as stated above in terms of the device, the invention is only defined by a pipette including a diaphragm with a pore, and a pump capable of creating a negative pressure. As previously stated the liquid (and or medium) is not an element of the device.

In view of the above remarks, the rejections repeated herein are hereby maintained.

Claim Rejections - 35 USC § 112

4. Claims 39-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 39 is directed to a new negative limitation not previously required. Where is such a claimed supported? If the medium is not liquid, then that implies the medium can be any other material such as gas, plasma, solid material such as fine powders, suspensions, etc. The medium should be claimed as positively of what it is rather than what it is not. In this case as stated above the medium as disclosed in the application is limited to gas or liquid.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 35-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase citing at least one pore of a given radius is unclear. The phrase "a given radius" is not a specified dimension as to determine what exactly is the dimension of the pore. A given radius can be any radius one chooses, for the claim places no limitations on the radius.

As to the claims citing the pump produces a negative pressure that does not go below a critical pressure to overcome liquid in the pore, the examiner asserts any vacuum pump or pump capable of creating a negative pressure is equivalent to the claimed pump for any pump can produce a negative pressure that will be greater than the critical pressure of some medium that exists.

It should be noted the effect in which a pump is going to have on a liquid present in the device will depend from a number of factors, including pore size, the type of particular liquid (viscosity), the type of material the diaphragm is manufactured from, surface tension of such material (is it hydrophobic or hydrophilic in reference to the particular liquid). Without specifying the factors as stated above the device and method as claimed will not function.

The equation of claims 37 and 43 are not further limiting of the structure, but state how one intends to calculate the critical pressure.

Claim 38 is directed to how the device is intended to be used. The medium is not positively claimed as an element of the apparatus.

Claim 39 is directed to a negative limitation which implies medium can be any other medium other that liquid. This is not supported by the specification.

As to claim 41, there are steps missing. The first step is providing the pipette, however while the second step is directed to producing a reduced pressure in relevance to a liquid. It is unclear where the liquid comes from and how it is related to the pipette. Is the liquid present in the pipette? Is the pipette placed in the liquid? If the pipette is placed in the liquid, but however such liquid is not taken up then how does one classify the method as a method of taking up a medium when the claim doesn't recite any medium ever entering the pipette? The method appears to be conventional for as presently drafted it is only directed to aspirating a liquid as explained above.

Claims 43-46 are not process limitations, for the claims do not add any additional steps to the method.

Claim Interpretations

7. For the purpose of examination, a system comprising an aspirating or vacuum device including a porous structure (filter, frit, membrane, disc with a hole/aperture, etc.) and pump capable of producing a negative pressure is considered equivalent to the device as claimed by applicant.

Claim Rejections - 35 USC § 102

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 35-46 rejected under 35 U.S.C. 102(b) as being anticipated by Bjorkman, US 4,642,220.

Bjorkman discloses a device for carrying out an analysis method. The device includes vessels 2 (pipettes) and the recesses 6 when the reaction vessels 2 are placed in the rack. In this way there is formed a plurality of chambers 8, which upwards are delimited by the porous bottom elements 3. Downwards the chambers 8 are connected to the channel 4. By using the connecting nipple 5, the channel 4 may be connected to a pressure regulating system (controller/mechanical control unit 25), e.g. to a suitable pump system for controlling the pressure of the chambers 8.

FIGS. 2 and 3 show two different types of reaction vessels, both of which have a porous bottom element 3. In addition thereto the vessel of FIG. 3 has a filter 9, which is applied to and covers the pores of the bottom element 3. For aqueous liquid phases the preferred filter is hydrophilic, particularly a three dimensional depth filter.

We have found that hydrophobic membranes with pore sizes from about 1μ to 20μ are useful for the reaction vessels shown in FIG. 2, especially when biospecific reactions are involved. It is suitable to work with pressure differentials between 100 and 500 Pa when using these types of porous bottoms (column 2, line 58).

10. Claims 35-46 rejected under 35 U.S.C. 102(b) as being anticipated by Moulton US 5,851,491.

Moulton discloses A filter (diaphragm) for a pipette tip is provided, comprising a plurality of vertically-oriented cylindrical micro fibers cohesively bundled in adjoining columns which are composed of a core of an autoclavable material and an outer coating

of a hydrophobic material. The micro fibers are packed together such that each micro fiber is compressed against the other fibers and the inner surface of the pipette tip. The compression of the fibers creates vertically-oriented pores interstitially between the micro fibers, each pore having a pore size at various points within the filter (abstract).

Filter 30 comprises a plurality of cylindrical micro fibers 44. Referring to FIGS. 3 and 4, micro fibers 44 each comprise a core 46 of an autoclavable material and an outer coating 48 of a hydrophobic material. In a first preferred embodiment, core 46 is formed of polypropylene and outer coating 48 is formed of polyethylene.

Pipettor 22 may be any suction device capable of drawing fluid 26 into pipette tip 12 in incremental amounts, including volumetric pipettors, elastic bulbs, bellows, or suction pumps.

11. Claims 35-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Kitajima et al., US 6,225,130.

Kitajima et al. disclose a method of preparing a serum sample from whole blood without destroying blood cells, and thereby, of obtaining highly reliable analytical values. The inventors found that, there is a critical value between the insertion speed of a serum suction nozzle into a vessel and a suction pressure, and a blood serum sample can be obtained without destruction of blood cells by sucking the blood serum while keeping the suction pressure under the critical value (Summary of Invention).

The holder body 10 (pipette) is made of high-impact polystyrene resin, and has a glass fiber filter chamber 11 for containing the glass fiber filter 30 and a microporous membrane chamber 12 for containing a polysulfone microporous membrane as the

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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brg

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